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| 09/600,848 | 08/22/2000 | Maria Pilar Prieto-Dapena | 1379-1-013 | 2038 |

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EXAMINER

GUZO, DAVID

ART UNIT

PAPER NUMBER

1636

15

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

09/600,848

Applicant(s)

PRIETO-DAPENA ET AL.

Examiner

David Guzo

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-34 and 37-48 is/are rejected.
- 7) ☒ Claim(s) 35 and 36 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 3/22/00 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Detailed Action

The Substitute Specification filed 5/19/03 is acceptable and has been entered.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-31, 33-34, 37-40, 42-43 and 45-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants disclose a genomic sequence (SEQ ID NO:1) encoding a Ha ds10 G1 gene product from sunflower plants. SEQ ID NO:1 includes 5' and 3' sequences, coding sequences and an intron. Applicants claim a genus of isolated nucleic acids, having promoter activity, comprising nucleotide sequences with at least 70% (and up to 95%) homology to SEQ ID NO:1 or a sequence complementary to SEQ ID NO:1 or fragments thereof, and with the functional limitation of the sequences or fragments thereof having an activity of SEQ ID NO:1. Applicants also claim chimeric genes comprising the aforementioned sequences or portions of SEQ ID NO:1, an expression cassette (vector) comprising said sequences, host cells comprising said sequences, transgenic plants comprising said sequences and methods of producing substances comprising transferring into plants the recited sequences or vectors.

The written description requirement for a claimed genus may be satisfied by sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or art recognized correlation between function and structure, or by a combination of such identifying characteristics sufficient to show applicant was in possession of the claimed genus.

In the instant case, applicants claim Ha ds10 G1 genes or promoters which have certain homologies to the single Ha ds10 G1 gene (and promoter) sequence disclosed by applicants and have an activity of the disclosed sequence. However, neither applicants nor the prior art discloses a relationship between the structure of the instantly disclosed sunflower Ha ds10 G1 gene and its function. Indeed, applicant indicates that the "distribution and accumulation pattern of Ha ds10 G1 is different from that presented by other plant genes belonging to the same family..." (Page 12 of the specification) and therefore comparisons between the Ha ds10 G1 gene and other members of the family to which it belongs may not be fruitful with regard to defining functional motifs. Applicants provide no relationship between the structure of the Ha ds10 G1 gene and the functional behavior of the protein encoded by said gene. Also, the regulatory elements of the gene (promoter regions, 3' regulatory sequences, etc.) cannot be predicted based upon the sequence of one example. These elements must be determined empirically. The disclosure of one example of a Ha ds10 G1 gene cannot therefore be considered to constitute a representative number of examples sufficient to

Art Unit: 1636

indicate to the skilled artisan that applicants were in possession of the claimed genus. Also, given the lack of a disclosed or art recognized relationship between the structure of the Ha ds10 G1 gene and its functions in the cell, it must be considered that the skilled artisan would not conclude that applicant was in possession of the claimed genus. Given that applicants were not in possession of the claimed genus of sequences, applicants were also not in possession of the expression cassettes, vectors, host cells and transgenic plants containing said sequences and the methods of use of said sequences to express proteins.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31-33, 40-41, 43-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 31-33, 40, 43 and 46 (and dependent claims) are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the other component of the "chimeric gene" Applicants claim chimeric genes but only recite one component of the chimeric gene (i.e. SEQ ID NO:1 or sequences complementary to SEQ ID NO:1 or fragments of SEQ ID NO:1 having an activity of SEQ ID NO:1) without reciting the other component(s) and how they are functionally or operably linked.

Art Unit: 1636

Claims 37-38 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the relationship between the "chimeric gene" and Ha ds10 G1 sequences (SEQ ID NO:1, sequences homologous thereto, etc.). It is unclear if the chimeric gene is comprised of the Ha ds10 G1 sequences and some other undisclosed sequence(s)?

No Claims are allowed.

Claims 35-36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 1636

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Faxes may be submitted directly to the examiner at (703) 746-5061.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David Guzo
August 5, 2003

DAVID GUZO
PRIMARY EXAMINER
David Guzo